

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

MEMORANDUM

10/30/2020

SUBJECT: Product Chemistry Review for **Neogen Viroxide Super** EPA Reg. No.: **66171-RNA**

FROM: Lynette T. Umez-Eronini

Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader

10/29/2020

Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Jacqueline Hardy, PM Team 34 / Karen Leavy
Regulatory Management Branch II
Antimicrobials Division (7510P)

Registrant: Preserve
International

Action Code: A572

Agency Due Date:
2/22/2020

DP No.: 458031

Submission No.: 1051299

E-Sub No.: 49751

Classification: EP

Process: Integrated
system

Pesticide type:
Antimicrobial

MRID(s):50934800, 50934816, 50934817, 50934818, 50934820, 50934821, 50934822,
50934823, 50934824, 50934825, 50934830, 50934833, 50934834, 50936101

| Formulation from label | | | |
|------------------------|------------|-----------------------------|----------|
| PC code(s) | CAS #(s) | Active Ingredient(s) | % weight |
| 063604 | 10058-23-8 | Potassium peroxymonosulfate | 22.41 |
| 013905 | 7647-14-5 | Sodium chloride | 1.50 |
| | | Other Ingredients | 76.09 |
| | | Total | 100.00 |

I. BACKGROUND

The Registrant, Preserve International, has submitted an application for pesticide registration for their product: Neogen Viroxide Super EPA Reg. No. 66171-RNA.

II. RELEVANT DOCUMENTS

| | RECEIVED | N/A |
|--|-------------------------------------|-------------------------------------|
| EPA FORM 8570-1 – Application for Pesticide-Registration (4/22/2020) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| EPA FORM 8570-27 – Formulator’s Exemption Statement | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| EPA FORM 8570-34 – Certification with Respect to Citation of Data (8/5/2020) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| EPA FORM 8570-35 – Data Matrix (7/20/2020) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Cover letter (4/28/2020) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Transmittal document (April 29, 2020) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Proposed CSF BASIC, ALTERNATE 1, ALTERNATE 2 (10/27/2020) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Proposed label, (6/12/2020) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Certification for Pilot Fragrance Notification Program | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | <input type="checkbox"/> | <input type="checkbox"/> |
| REFERENCED: CSF | -- | |
| Comments: | | |

III. FINDINGS

a. Product Formulation:

| | TGAI | MUP | EUP | Food use | Non-food use |
|-----------------------------|--------------------------|--------------------------|-------------------------------------|--------------------------|-------------------------------------|
| Non-integrated | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Integrated | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | | | | | |
| Active Ingredients(s) | | | Nominal | Upper limit | Lower limit |
| Potassium Peroxymonosulfate | | | 22.41 | 23.08 | 21.73 |
| Sodium Chloride | | | 1.50 | 1.57 | 1.42 |
| | | | | | |
| | | | YES | NO | N/A |

| | | | |
|---|-------------------------------------|--------------------------|-------------------------------------|
| 1. The certified limits of all ingredients are within 40 CFR standard certified limits. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 2. Wider certified limits were requested and rationale was accepted. | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 3. The nominal concentration(s) of the active ingredient is in agreement with the label. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 5. All inert ingredients are approved for non-food use pesticide formulations. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. The impurities present >0.1% are identified. | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7. Impurities of toxicological significance have an upper certified limit. | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

b. Product Label:

| | Yes | NO | N/A |
|---|-------------------------------------|-------------------------------------|-------------------------------------|
| <i>The formula contains one of the following:</i> | | | |
| 1. 10% or more of petroleum distillate | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 2. 1.0% or more of methyl alcohol | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 3. Sodium nitrite at any level | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 4. A toxic list 1 inert at any level | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 5. Arsenic in any form | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 6. If yes to 1-5, then the inert ingredient list contains a relevant footnote | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses. | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit. | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

IV. Additional Findings

1. Group A product chemistry data requirements applicable to an end-use product have been met (see Table A below).
2. The 14-Day Accelerated 830.6317 Storage Stability and 830.6320 Corrosion Characteristics studies require upgrading for not reporting the concentration of active ingredients at start and end of the testing period.

3. Group B product chemistry data requirements applicable to an end-use product have been met (see Table B below), except the 830.6317 Storage Stability and 830.6320 Corrosion Characteristics guidelines. The unmet guidelines must be sent upon completion.
4. Basic and Alternate #1 and #2 CSFs dated 10/27/2020 are acceptable.

V. Conclusion

The Product Science Branch of Antimicrobials Division finds Group A and B Product Chemistry Data requirements have been met, except the 830.6317 Storage Stability and 830.6320 Corrosion Characteristics guidelines. The unmet guidelines must be sent upon completion. Basic and Alternate # 1 and #2 CSFs dated 10/7/2020 are acceptable.

VI. Table A:
Series 830 guidelines – Group A

| OPPTS# | Name | Status | MRID |
|----------|---------------------------------------|--------------------|-------------------------------------|
| 830.1550 | Product Identity & Composition | Acceptable | 50934816 50934834 |
| 830.1600 | Description of materials | Acceptable | 50934816 50934834 |
| 830.1620 | Description of production process | Acceptable | |
| 830.1650 | Description of formulation process | Acceptable | 50934816 |
| 830.1670 | Discussion of formation of impurities | Acceptable | 50934816 |
| 830.1700 | Preliminary analysis | Acceptable | 50934817 50936101 |
| 830.1750 | Certified limits | Acceptable | 50934816 |
| 830.1800 | Enforcement analytical method | Requires upgrading | 50934818 |
| 830.1900 | Submittal of samples | Acceptable | Registrant's email, dated 6/16/2020 |

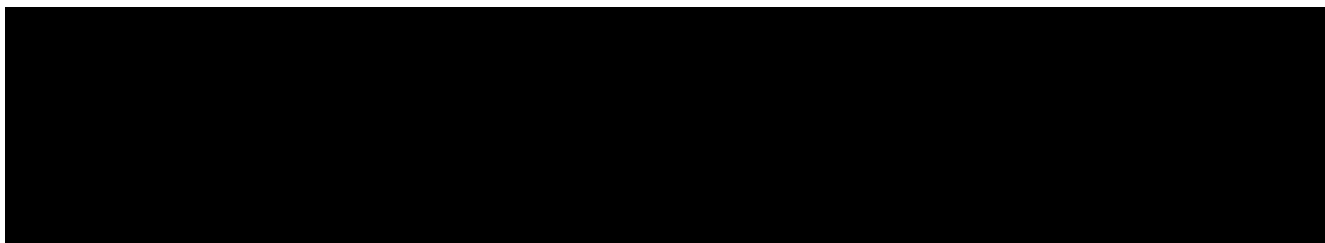
Product ingredient source information may be entitled to confidential treatment

VII. Table B: Series 830 guidelines – Group B

| OPPTS# | Name | Study Findings/Comment | | | | Status | MRID |
|----------|--|--|------------|------------|-------------|--------------------|----------|
| 830.6302 | Color | Not required for end use product. Registrant reported, green/blue color | | | | Not applicable | 50934820 |
| 830.6303 | Physical state | Powder | | | | Acceptable | 50934820 |
| 830.6304 | Odor | Not required for end use product. Registrant reported a sweet odor (synthetic apple fragrance). | | | | Not applicable | 50934820 |
| 830.6313 | Stability to normal & elevated temperatures, metals & metal ions | The product is not TGA | | | | Not applicable | N/A |
| 830.6314 | Oxidation/Reduction | Waiver requested. This product is a strong oxidizer. | | | | Acceptable | 50934821 |
| 830.6315 | Flammability | Waiver requested. Product is a powder and is not flammable. | | | | Acceptable | 50934822 |
| 830.6316 | Explodability | Waiver requested. Product is a free-flowing powder that is not explosive on its own. | | | | Acceptable | 50934823 |
| 830.6317 | Storage stability (14-Day Accelerated) | Study failed to report the concentration of both active ingredients at start and end of the study. | | | | Requires upgrading | 50935801 |
| 830.6319 | Miscibility | Waiver requested. Product is a powder that is intended to be mixed with water and should not be mixed with solvents. | | | | Acceptable | 50934824 |
| 50934820 | Corrosion characteristics | Study requires upgrading since it is done along with the Storage Stability. | | | | Requires upgrading | 50935801 |
| 830.6321 | Dielectric breakdown voltage | Waiver Requested. It is not recommended that product solutions be used on electrical equipment. | | | | Acceptable | 50934825 |
| 830.7000 | pH | 2.40 at 20C | | | | Acceptable | 50935801 |
| 830.7050 | UV/Visible absorption | Not required for MUP or EP | | | | Not applicable | N/A |
| 830.7100 | Viscosity | | 50 rpm | 60 rpm | 100 rpm | Acceptable | 50934820 |
| | | Viscosity, mPa·s at 20±0.1°C | 7.40 ±0.00 | 8.53 ±0.00 | 11.28 ±0.05 | | |

| | | | | | | | |
|----------------------------|---------------------------------|---|---|---------------|---------------|----------------|----------|
| | | Viscosity, mPa·s at 40±0.1°C | — | 6.36 ±0.05 | 8.88 ±0.00 | | |
| 830.7200 | Melting point | Not required for MUP or EP | | | | Not applicable | N/A |
| 830.7220 | Boiling point | Not required for MUP or EP | | | | Not applicable | N/A |
| 830.7300 | Density/relative | Avg Pour Density – 1.1134g/mL Avg Tap Density – 1.1926g/mL | | | | Acceptable | 50934820 |
| 830.7370 | Dissociation constants in water | Not required for MUP or EP | | | | Not applicable | N/A |
| 830.7520 | Particle size | Not required for MUP or EP | | | | Not applicable | N/A |
| 830.7550/ 7560/ 7570 | Partition coefficient | Not required for MUP or EP | | | | Not applicable | N/A |
| 830.7840/ 7860 | Water solubility | Not required for MUP or EP | | | | Not applicable | N/A |
| 830.7950 | Vapor pressure | Not required for MUP or EP | | | | Not applicable | N/A |

CONFIDENTIAL ATTACHMENT



Product ingredient source information may be entitled to confidential treatment

From: [Eronini, Lynette](#)
To: [Leavy, Karen](#)
Cc: [Hicks, Karen](#); [Hardy, Jacqueline](#)
Subject: RE: 10-day Product Chemistry Technical Screen Failure letter for EPA File Symbol 66171-RNA - TECHNICAL SCREEN FOR 66171-RNA_D458031_Neogen Viroxide PASSED
Date: Tuesday, June 16, 2020 2:28:00 PM
Attachments: [image001.png](#)

Karen,

Registrant's response to the 830.1900 guideline overcame the technical screen failure. From a chemistry point of view, the technical screen for 66171-RNA_D458031_ **Neogen Viroxide passed.**

Note: Passing a technical screen is not an indication of a favorable chemistry review.

Lynette T. Umez-Eronini

From: Leavy, Karen <Leavy.Karen@epa.gov>
Sent: Tuesday, June 16, 2020 1:43 PM
To: Eronini, Lynette <Eronini.Lynette@epa.gov>
Subject: FW: 10-day Product Chemistry Technical Screen Failure letter for EPA File Symbol 66171-RNA

Good afternoon Lynette,

Let me know if this will do it for you. Please read the email below.

KML

From: Patrice Fields <PFIELDS@neogen.com>
Sent: Tuesday, June 16, 2020 1:36 PM
To: Leavy, Karen <Leavy.Karen@epa.gov>
Subject: RE: 10-day Product Chemistry Technical Screen Failure letter for EPA File Symbol 66171-RNA

Hi Karen,

Preserve International is in receipt of the 10-day product chemistry technical screen failure letter for 66171-RNA. The letter finds that Preserve International did not address OPPTS guideline 830.1900, submittal of samples. Preserve International will send samples upon request. If further actions are required to address this deficiency letter, please let me know.

Patrice



Patrice R. Fields
Registration Manager
Cleaners and Disinfectants

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620 Leshar Place, Lansing, MI USA 48912

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From: Leavy, Karen [<mailto:Leavy.Karen@epa.gov>]

Sent: Tuesday, June 16, 2020 12:49 PM

To: Patrice Fields <PFIELDS@neogen.com>

Subject: Re: 10-day Product Chemistry Technical Screen Failure letter for EPA File Symbol 66171-RNA

Good afternoon Ms. Fields,

Attached above is the 10-day Product Chemistry Technical Screen Failure for EPA File Symbol 66171-RNA.

KML